

AMENDED IN SENATE JANUARY 14, 2014

AMENDED IN SENATE MAY 7, 2013

AMENDED IN SENATE APRIL 22, 2013

AMENDED IN SENATE APRIL 1, 2013

**SENATE BILL**

**No. 222**

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**Introduced by Senator Padilla**

February 11, 2013

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An act to add Chapter 2.6 (commencing with Section 56.18) to Part 2.6 of Division 1 of the Civil Code, relating to genetic information.

LEGISLATIVE COUNSEL'S DIGEST

SB 222, as amended, Padilla. Genetic information: privacy.

Existing law prohibits discrimination on the basis of an individual's genetic information. Existing law protects the genetic test result contained in the medical records of an applicant to, or enrollee of, a health care service plan. Existing law establishes civil and criminal penalties for the negligent or willful disclosure of a persons genetic test results, as specified.

This bill would enact the Genetic Information Privacy Act, which would declare that an individual's genetic information is protected by the right of privacy. The bill would prohibit any person from ~~collecting, storing, analyzing, or disclosing genetic information~~ *obtaining or analyzing a DNA sample, as defined*, without the written authorization of the individual to whom the ~~information~~ *DNA sample* pertains, and would include related findings and declarations. It also would prescribe specific circumstances under which ~~genetic information~~ *a DNA sample* may be ~~collected, obtained, stored, or analyzed~~, or *genetic test results* disclosed, without the authorization. The bill would establish civil and

criminal penalties for a violation of its provisions. By creating new crimes, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
 State-mandated local program: yes.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) On October 11, 2012, the Presidential Commission for the
- 4 Study of Bioethical Issues (commission) released a report titled
- 5 “Privacy and Progress in Whole Genome Sequencing,”
- 6 recommending the ~~adoption~~ *adoption* of policies to help ensure
- 7 privacy and security, as the field of genomics advances.
- 8 (b) Various national and state policies are in place to ~~protect~~
- 9 ~~personally identifiable health information and records.~~ *effectively*
- 10 *protect individually identifiable health information, biosamples*
- 11 *used in academic research and records, including genetic*
- 12 *information.*
- 13 ~~(c) The commission urges federal and state governments to~~
- 14 ~~ensure a consistent floor of privacy protections covering whole~~
- 15 ~~genome sequencing data regardless of how they were obtained.~~
- 16 ~~(d)~~
- 17 (c) Policies should protect individual genetic information by
- 18 prohibiting the unauthorized use of surreptitious collection.
- 19 (d) *It is the intent of the Legislature to enact legislation to extend*
- 20 *established protections to individually identifiable genetic*
- 21 *information not covered by existing national or state policies.*
- 22 (e) It is the intent of the Legislature to enact legislation that
- 23 would protect individuals from the unauthorized collection, storage,
- 24 ~~and disclosure of their genetic information.~~ *and analysis of their*
- 25 *DNA samples and genetic characteristics.*
- 26 ~~(f) It is the intent of the Legislature to enact legislation that~~
- 27 ~~would ensure that genetic information is personal information that~~

1 is not collected, stored, or disclosed without the individual's  
2 authorization.

3 ~~(g) It is the intent of the Legislature to enact legislation that  
4 would provide protections for the collection, storage, and  
5 authorized use of genetic information.~~

6 ~~(h)~~

7 (f) It is the intent of the Legislature to enact legislation that  
8 would promote the use of genetic information for legitimate  
9 reasons, including, but not limited to, health care, research,  
10 advancement of medicine, and educational purposes, as the field  
11 of genomics advances.

12 SEC. 2. Chapter 2.6 (commencing with Section 56.18) is added  
13 to Part 2.6 of Division 1 of the Civil Code, to read:

14

15 CHAPTER 2.6. GENETIC PRIVACY

16

17 56.18. (a) This chapter shall be known, and may be cited, as  
18 the Genetic Information Privacy Act.

19 (b) For purposes of this chapter, the following definitions apply:

20 (1) "Deidentified data" is health information that does not  
21 identify an individual, with respect to which there is no reasonable  
22 basis to believe that the information can be used to identify an  
23 individual, *in accordance with Section 164.514 of Title 45 of the*  
24 *Code of Federal Regulations.*

25 (2) "DNA sample" means ~~a tissue, fluid, or other bodily sample~~  
26 ~~of an individual on which a DNA analysis can be carried out.~~ *a*  
27 *human biological specimen that is obtained or retained for the*  
28 *purpose of extracting and analyzing DNA to perform a genetic*  
29 *test.*

30 (3) "Genetic characteristic" ~~means any gene or chromosome,~~  
31 ~~or alteration thereof, that may be tested to determine the existence~~  
32 ~~or risk of a disease, disorder, trait, propensity, or syndrome, or to~~  
33 ~~identify an individual or a blood relative, or to establish or disprove~~  
34 ~~paternity, or to achieve other non-health-related purposes.~~ *includes*  
35 *a gene, chromosome, or alteration thereof that may be tested to*  
36 *determine the existence or risk of a disease, disorder, trait,*  
37 *propensity, or syndrome, or to identify an individual or a blood*  
38 *relative.*

39 (4) (A) "Genetic information" means information about any of  
40 the following:

- 1     ~~(i) An individual’s genetic tests.~~  
 2     ~~(ii) The genetic tests of that individual’s family members.~~  
 3     ~~(iii) The manifestation of disease or disorder in family members~~  
 4     ~~of the individual, generally referred to as family medical history.~~  
 5     ~~(iv) An individual’s request for, or receipt of, genetic services,~~  
 6     ~~or the participation in clinical research that includes genetic~~  
 7     ~~services by the individual or a family member of the individual.~~  
 8     ~~(v) The genetic information of a fetus carried by an individual~~  
 9     ~~or by a pregnant woman who is a family member of the individual~~  
 10    ~~and the genetic information of any embryo legally held by the~~  
 11    ~~individual or family member using an assisted reproductive~~  
 12    ~~technology.~~  
 13    ~~(B) “Genetic information” also includes a DNA sample.~~  
 14    ~~(5) “Genetic service” means a genetic test, genetic education,~~  
 15    ~~or genetic counseling, including obtaining, interpreting, or~~  
 16    ~~assessing genetic information.~~  
 17    ~~(6)~~  
 18    ~~(4) “Genetic test” means a test for determining the presence or~~  
 19    ~~absence of genetic characteristics in the individual or in the~~  
 20    ~~individual’s blood relatives, including tests of nucleic acids such~~  
 21    ~~as DNA, RNA, and mitochondrial DNA, chromosomes, or proteins,~~  
 22    ~~in order to diagnose or determine a genetic characteristic.~~  
 23    ~~(7)~~  
 24    ~~(5) “Person” means a natural person, trust or estate, partnership,~~  
 25    ~~corporation, limited liability company, professional association or~~  
 26    ~~corporation, or other entity, public or private.~~  
 27    56.18.1. ~~(a) Genetic test information is protected by the right~~  
 28    ~~of privacy pursuant to Section 1 of Article I of the California~~  
 29    ~~Constitution and, notwithstanding subdivision (e) of Section 56.10,~~  
 30    ~~or any other law, shall not be collected, stored, analyzed, or~~  
 31    ~~disclosed without the written authorization of the individual to~~  
 32    ~~whom the information pertains. Constitution. A DNA sample shall~~  
 33    ~~not be obtained or analyzed without the written authorization of~~  
 34    ~~the individual to whom the DNA sample pertains.~~  
 35    ~~(b) Any~~ A person who negligently violates subdivision (a) shall  
 36    be assessed a civil penalty in an amount not to exceed one thousand  
 37    dollars (\$1,000) plus court costs, as determined by the court, which  
 38    penalty and costs shall be paid to the individual to whom the  
 39    ~~genetic information-DNA sample~~ pertains.

1 (c) ~~Any~~ A person who willfully violates subdivision (a) shall  
2 be assessed a civil penalty in an amount not less than one thousand  
3 dollars (\$1,000) and not more than five thousand dollars (\$5,000)  
4 plus court costs, as determined by the court, which penalty and  
5 costs shall be paid to the individual to whom the ~~genetic~~  
6 ~~information~~ DNA sample pertains.

7 (d) ~~Any~~ A person who willfully or negligently violates  
8 subdivision (a), ~~where~~ and the violation results in economic, bodily,  
9 or emotional harm to the individual to whom the ~~genetic~~  
10 ~~information~~ DNA sample pertains, is guilty of a misdemeanor  
11 punishable by a fine not to exceed ten thousand dollars (\$10,000).

12 (e) In addition to the penalties listed in subdivisions (b) and (c),  
13 a person who commits an act described in subdivision (b) or (c)  
14 shall be liable to the person to whom the ~~genetic information~~ DNA  
15 sample pertains for all actual damages, including damages for  
16 economic, bodily, and emotional harm that is proximately caused  
17 by that act.

18 (f) Each violation of this section is a separate and actionable  
19 offense.

20 (g) *A laboratory that performs a genetic test shall be deemed*  
21 *in compliance with subdivision (a) if the laboratory believes, in*  
22 *good faith and in the absence of knowledge to the contrary, that*  
23 *a written consent by the individual to whom the DNA sample*  
24 *pertains is valid.*

25 ~~(g) (1) Any~~

26 (h) *Except as provided in subdivision (i), a person or entity that*  
27 *wishes to obtain genetic information, other than a person or entity*  
28 *authorized to receive genetic information pursuant to subdivision*  
29 *(h), shall obtain a valid authorization for the release of that*  
30 *information. or analyze a DNA sample, shall obtain a valid*  
31 *authorization from the individual to whom the DNA sample*  
32 *pertains. The written authorization required by this subdivision*  
33 *shall do all of the following:*

34 (A)

35 (1) Be written in plain language and in a typeface no smaller  
36 than 14-point type.

37 (B)

38 (2) Be dated and signed by the individual or a person authorized  
39 to act on behalf of the individual.

40 (C)

- 1 (3) Specify the types of persons authorized to ~~disclose~~  
2 ~~information~~ *obtain a DNA sample and analyze and disclose the*  
3 *genetic test results* about the individual.
- 4 (D)
- 5 (4) Specify the nature of the ~~information~~ authorized to be  
6 ~~disclosed~~. *genetic test results authorized to be obtained and*  
7 *analyzed.*
- 8 (E)
- 9 (5) State the name or functions of the persons or entities  
10 authorized to receive the ~~information~~. *genetic test results.*
- 11 (F)
- 12 (6) Specify the purposes for which the ~~information~~ *DNA sample*  
13 *is being collected.*
- 14 (G)
- 15 (7) Specify the length of time the authorization shall remain  
16 valid.
- 17 (H)
- 18 (8) Advise the person signing the authorization of his or her  
19 right to control the use of his or her ~~genetic information~~ *DNA*  
20 *sample and test results.*
- 21 (I) ~~Advise the person signing the authorization of his or her~~  
22 ~~right to revoke authorization at any time.~~
- 23 (J) ~~Advise the person signing the authorization as to whether~~  
24 ~~his or her information will remain identifiable or whether measures~~  
25 ~~will be taken to make the information nonidentifiable.~~
- 26 (K)
- 27 (9) Advise the person signing the authorization that the genetic  
28 ~~information~~ *test results* and *DNA* sample provided must be  
29 destroyed upon achieving that purpose.
- 30 (L)
- 31 (10) Advise the person signing the authorization of the right to  
32 receive a copy of the authorization. *Written authorization is*  
33 *required for each separate disclosure of the genetic test results.*
- 34 (2)
- 35 (i) Any person who collects, stores, or analyzes *the DNA sample*,  
36 or discloses the genetic ~~information~~ *test results*, of an individual  
37 shall comply with all of the following:
- 38 (A)
- 39 (1) The person may not collect, store, or analyze *the DNA*  
40 *sample*, or disclose the genetic ~~information~~ *test results* for any

1 purpose other than the purpose authorized by the individual to  
2 whom the ~~information pertains~~. *DNA sample or genetic test results*  
3 *pertain.*

4 ~~(B)~~

5 (2) Once the specific purpose authorized by the individual to  
6 whom the ~~genetic information pertains~~ *test results pertain* has been  
7 fulfilled, the individual’s ~~genetic information~~ *test results* and DNA  
8 sample shall be destroyed.

9 ~~(C)~~

10 (3) The person shall permit an individual to revoke an  
11 authorization signed pursuant to ~~paragraph (1) subdivision (h)~~ at  
12 any time.

13 ~~(D)~~

14 (4) The person shall provide an individual who has signed an  
15 authorization pursuant to ~~paragraph (1) subdivision (h)~~ with a copy  
16 of that authorization upon request.

17 ~~(h)~~

18 (j) (1) ~~Genetic information~~ *A DNA sample* may be ~~collected~~  
19 *obtained*, stored, or analyzed, ~~or and genetic test results~~ disclosed  
20 without the authorization required by subdivision ~~(g) (h)~~, in  
21 accordance with paragraph (2), ~~provided that the entity may collect,~~  
22 ~~store, analyze, or disclose the information~~ only for the purposes  
23 specified. Use for any other purpose is subject to the authorization  
24 required by subdivision (a).

25 (2) ~~Genetic information~~ *A DNA sample* may be ~~collected,~~  
26 *obtained*, stored, or analyzed, ~~or and genetic test results~~ disclosed,  
27 under this subdivision, as follows:

28 (A) By a law enforcement official or correctional officer in the  
29 execution of his or her official duties consistent with existing law.

30 (B) By a hospital, laboratory, or physician carrying out  
31 court-ordered tests for genetic information, *in the execution of his*  
32 *or her official duties consistent with existing law.*

33 ~~(C) By a licensed health care professional, as defined in Section~~  
34 ~~56.05, in a medical emergency.~~

35 ~~(D) By a coroner or medical examiner, in the execution of his~~  
36 ~~or her official duties consistent with existing law.~~

37 ~~(E) For purposes of any screening of a newborn infant required~~  
38 ~~by state or federal law.~~

39 (C) *By a coroner or medical examiner, in the execution of his*  
40 *or her official duties consistent with existing law.*

- 1 (D) By a federal, state, or local governmental entity, or  
 2 contractor or designee of that governmental entity in the execution  
 3 of his or her official duties consistent with existing law.
- 4 ~~(F)~~
- 5 (E) If the information is in the form of deidentified data.
- 6 ~~(G)~~
- 7 ~~(F) By any person or entity covered by and required to comply~~  
 8 ~~with any of the following:~~
- 9 ~~(i) The Health Insurance Portability and Accountability Act of~~  
 10 ~~1996 (Public Law 104-191).~~
- 11 ~~(ii) Section 56.11 of the Confidentiality of Medical Information~~  
 12 ~~Act (Part 2.6 (commencing with Section 56)).~~
- 13 ~~(iii) Section 791.13, 10123.35 or Article 2.6 (commencing with~~  
 14 ~~Section 10146) of Chapter 1 or Part 2 of Division 2 of the Insurance~~  
 15 ~~Code.~~
- 16 ~~(iv) Section 50.25 of Title 21 of the Code of Federal~~  
 17 ~~Regulations.~~
- 18 ~~(v) Section 46.116 of Title 28 of the Code of Federal~~  
 19 ~~Regulations.~~
- 20 (i) A person or entity covered by and required to comply with  
 21 Section 56.11 of the Confidentiality of Medical Information Act  
 22 (Part 2.6 (commencing with Section 56)).
- 23 (ii) A person or entity covered by and required to comply with  
 24 Section 791.13, 10123.35, or Article 2.6 (commencing with Section  
 25 10146) of Chapter 1 of Part 2 of Division 2 of the Insurance Code.
- 26 (iii) A licensed health care professional or designee of a licensed  
 27 health care professional. “Licensed health care professional”  
 28 means any person licensed or certified pursuant to Division 2  
 29 (commencing with Section 500) of the Business and Professions  
 30 Code, the Osteopathic Initiative Act or the Chiropractic Initiative  
 31 Act, or Division 2.5 (commencing with Section 1797) of the Health  
 32 and Safety Code.
- 33 (iv) A provider of health care or a designee of a provider of  
 34 health care. “Provider of health care” means a health facility  
 35 licensed pursuant to Division 2 (commencing with Section 1200)  
 36 of the Health and Safety Code.
- 37 (v) A covered entity, business associate, or subcontractor as  
 38 those terms are defined in the federal Health Insurance Portability  
 39 and Accountability Act of 1996 (Public Law 104-191) and its  
 40 implementing regulations.

1 (vi) *An investigator within an institution, or working in*  
2 *collaboration with an institution, that holds an assurance with the*  
3 *United States Department of Health and Human Services pursuant*  
4 *to Part 46 (commencing with Section 46.101) of Title 45 of the*  
5 *Code of Federal Regulations and who obtains informed consent*  
6 *or who qualifies for an exemption from informed consent in the*  
7 *method and manner required by those regulations.*

8 (vii) *A pharmaceutical company. “Pharmaceutical company”*  
9 *means a company or business, or an agent or representative*  
10 *thereof, that manufactures, sells, or distributes pharmaceuticals,*  
11 *medications, or prescription drugs pursuant to regulations of the*  
12 *federal Food and Drug Administration, and that either obtains*  
13 *informed consent, or qualifies for an exemption from informed*  
14 *consent in the method and manner required by those regulations.*

15 SEC. 3. No reimbursement is required by this act pursuant to  
16 Section 6 of Article XIII B of the California Constitution because  
17 the only costs that may be incurred by a local agency or school  
18 district will be incurred because this act creates a new crime or  
19 infraction, eliminates a crime or infraction, or changes the penalty  
20 for a crime or infraction, within the meaning of Section 17556 of  
21 the Government Code, or changes the definition of a crime within  
22 the meaning of Section 6 of Article XIII B of the California  
23 Constitution.